Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 1001.2219102

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Application Number	Filed
10/595,977	June 14, 2007

First Named Inventor: Mark Ashby

Art Unit	Examiner
3773	Mark F. Mashack

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 36,926.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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April 5, 2012
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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Appln. Ser. No. 10/595,977

PRE-APPEAL CONFERENCE BRIEF

Appellants have carefully reviewed the Final Office Action of January 6, 2012 and the Advisory Action of March 12, 2012. Currently, claims 1, 27, 29-33, 40-42, 44-49, and 61-62 are pending in the application, claims 29-33 having been previously withdrawn. Claims 1, 27, and 61-62 are allowed. Claims 40-42, 44, and 46-49 stand rejected under 35 U.S.C. 102(e) over Houser et al. (U.S. Patent No. 6,726,696). Claim 45 stands rejected under 35 U.S.C. 103(a) over Houser in view of Briganti et al. (U.S. published Patent Application No. 2005/0033326). Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Initially, it should be noted that Appellants have offered a clarifying amendment to independent claim 40 which was not entered by the Examiner. The assertion is made that the amendment raises new questions that would require further consideration and/or search. It is Appellants' position that the meaning of "body" as used in original claim 40 was adequately described at page 21, last line:

> "Body 406 may be any hemostatic material such as the hemostatic material detailed above."

No other description of the body portion of the device as recited in claim 40 has been presented. The initial search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed. See MPEP § 904.02. It was incumbent upon the Examiner to have searched the art in view of the presence of a hemostatic body within the device of original claim 40 as the body portion of such a device is described within the specification.

> "Rather, the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification."

The proposed amendment, although not believed to be necessary because it does not alter the specification's clear indication of the nature of the element identified as a body, should not have occasioned either further consideration and/or search for the reason that the body of claim 40 has always been a body of hemostatic material and thus a hemostatic material body.

Proceeding to a consideration of the rejection of claim 40 under §102(e), Appellants substantially repeat the earlier argument:

> Nowhere does Houser appear to teach or suggest:
>
> "a hemostatic [material] body to seal the blood vessel puncture site; and a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body", as recited in claim 40.

Instead, Houser appears to teach a mechanical arterial closure device, for example device 105 of Fig. 4, "partially or completely fabricated from a biodegradable/bioabsorbable material" (col. 6, lines 13-14), which functions as a mechanical plug to close a blood vessel puncture. Houser does not appear to disclose that the arterial closure device 105 is hemostatic by virtue of the materials from which it may formed and indeed if it were the case that the plug material were hemostatic, that portion 140 of the plug which is disposed within the blood vessel would be expected to initiate and grow a thrombus with a significant attendant risk that the thrombus would grow to block the blood vessel in which portion 140 of the plug is deployed and/or that the thrombus would shed with serious consequences for tissue downstream.

The Examiner initially erred at page 2 of the final Office Action by assuming that all bodies 145 of Houser are "hemostatic bodies" by virtue of being formed from collagen. Appellants have noted that the term "collagen" does not describe a single material, but rather the literature describes up to 16 types of collagen, some of which are characterized as nonhemostatic as, for example in the closure devices of U.S. Patent 5,192,302 to Kensey et al.:

> "Irrespective of the manner by which the plug member is formed, it is preferable that at least its distally located portion is formed of a non-hemostatic material, such as polyglycolic acid, polylactide, polylactic acid, nonthrombogenic collagen, or combinations thereof."
> (Col. 9, lines 23-28.)

In the case of the unitary plug 105 of Houser, the entire plug including first member 140, second member 145, connecting member 150, and extending member 155 appears to be made of

a single material. If the disclosed plug 105 is made of collagen rather than one of the other suitable materials, some of which also appear to be non-hemostatic, it does not appear inherently to be the case that the collagen of the plug is hemostatic in other than in the mechanical blockage sense upon which Houser relies.

In the Advisory Action of March 12, 2012, the Examiner errs in failing to appreciate that the hemostatic body of claim 40 is made from a hemostatic material as described in the specification and as discussed herein and further errs in attempting to avoid responding to Appellants' argument that one of ordinary skill in the art in view of the specification would have appreciated that the claimed hemostatic body is a hemostatic material body by now asserting instead that the device of Houser, not the element corresponding to the body of claim 40, is hemostatic because, as a device, it is mechanically capable of stopping blood flow.

The current rejection depends upon the incorrect assumption that at least second member 145, generally occupying a position corresponding to the body element of claim 40, is inherently a hemostatic material, a property not disclosed by Houser. Further, Houser does not teach an intravascular flexible disk "being sufficiently flexible to conform to and seal with the blood vessel puncture site". First member 140 of Houser is not disclosed as being flexible. Instead, Houser characterizes cited ACD 105 as having "sufficient rigidity to be advanced through the puncture site 125" (col. 5, lines 26-26) and further describes the vessel wall as elastically recovering upon passage of ACD 105 thereby indicating that it is the vessel wall which flexes as first member 140 passes through the puncture. In the absence of an inherently hemostatic plug 105 and a flexible intravascular disk, Houser does not appear to disclose, explicitly or inherently, each and every element set forth in independent claim 40, and Applicants respectfully request that the rejection of claim 40 be overruled.

Claims 41, 42, 44, and 46-94 depend from unanticipated independent claim 40 and add significant additional limitations thereto. Accordingly those claims also are not anticipated by Houser and Appellants respectfully request that the rejections be overruled.

With regard to the rejection of claim 45, Appellants note that Houser does to teach all teach all the claim limitations of independent claim 40, as is required to establish a *prima facie* case of obviousness. Briganti is asserted to disclose a vascular plug with a release mechanism comprising a suture looped through a resilient extension member; however independent claim 40 does not recite a release mechanism, a resilient extension member, or a suture looped

therethrough as a limitation. Accordingly, the disclosure of Briganti does not appear to overcome the deficiencies of Hauser as applied to independent claim 40.

> If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Claim 45, which depends from nonobvious independent claim 40, also is nonobvious and Appellants respectfully request that the rejection be overruled.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: Apr. 15, 2012

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